

Exhibit 8

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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL)	
PRESCRIPTION)	MDL No. 2804
OPIATE LITIGATION)	
_____)	Case No.
)	1:17-MD-2804
)	
THIS DOCUMENT RELATES)	Hon. Dan A.
TO ALL CASES)	Polster

WEDNESDAY, APRIL 24, 2019

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CONFIDENTIALITY REVIEW

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Videotaped deposition of Anna
Lembke, M.D., held at the offices of Lief
Cabreraser Heimann & Bernstein, LLP, 275
Battery Street, 29th floor, San Francisco,
California, commencing at 8:07 a.m., on the
above date, before Carrie A. Campbell,
Registered Diplomat Reporter and Certified
Realtime Reporter.

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<p>1 would hold yourself out as a psychiatrist as 2 opposed to a pain management physician or an 3 anesthesiologist? 4 MR. ARBITBLIT: Object to form. 5 THE WITNESS: I would disagree 6 with that statement because I do hold 7 myself out as having expertise in the 8 field of pain management, but not 9 anesthesiology, per se. 10 QUESTIONS BY MR. TSAI: 11 Q. How many hours have you spent 12 treating patients in palliative care, for 13 example, for their individual pain needs? 14 A. I have not worked in a 15 palliative care setting. 16 Q. How many patients have you 17 diagnosed with chronic pain as another 18 example? 19 A. I have diagnosed many patients 20 with chronic pain over the years. I've been 21 in practice for more than 20 years, seen 22 approximately 40,000 patients over my career. 23 I couldn't tell the exact number that I've 24 diagnosed with chronic pain, but if I had to 25 put a ballpark estimate, I would say</p>	<p>1 peer-reviewed research studies or articles 2 you've authored in the field of 3 anesthesiology, pain medicine or hospice and 4 palliative medicine? 5 A. I've authored two peer-reviewed 6 articles in pain medicine journals, but I 7 have written more broadly on the issue of 8 pain vis-à-vis the opioid epidemic, and so 9 that more broad area would include more of my 10 publications. 11 Q. And focusing on the two 12 articles in Pain Medicine journals, what were 13 the subject matters of those two articles? 14 A. The subject matter of those two 15 articles in Pain Medicine journals had to do 16 with perioperative management of opioid 17 agonist treatments such as buprenorphine and 18 methadone. 19 Q. Who retained you as a 20 testifying witness in this case? 21 A. Lieff Cabraser Heimann & 22 Bernstein. 23 Q. And do you know who they 24 represent? 25 A. They represent the MDL.</p>
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<p>1 something on the order of 50 percent of my 2 patients have some kind of chronic pain 3 diagnosis. 4 Q. What is the total number of 5 patients you've treated for their individual 6 pain needs as opposed to addiction associated 7 with surgeries or cancer? 8 MR. ARBITBLIT: Object to form. 9 THE WITNESS: It's difficulty 10 for me to put an exact number on that. 11 The majority of patients that I treat 12 for their pain needs also have some 13 sort of co-occurring mental health 14 disorder, but pain is a priority in 15 the overall treatment plan of those 16 patients. 17 QUESTIONS BY MR. TSAI: 18 Q. So just to be clear, in your 19 practice, you engage in primary diagnoses of 20 patients who are complaining of pain and 21 deciding how to treat their pain needs? 22 MR. ARBITBLIT: Objection. 23 THE WITNESS: Yes. 24 QUESTIONS BY MR. TSAI: 25 Q. What is the total number of</p>	<p>1 Q. Can you be more specific? 2 A. They represent the plaintiffs 3 in this case. 4 Q. And who are the plaintiffs in 5 this case? 6 A. The plaintiffs are the counties 7 and other entities who have been harmed as a 8 result of the opioid epidemic. 9 Q. Which counties? 10 A. There are too many counties 11 to -- I guess the bellwether counties would 12 be Cuyahoga and Summit Counties in Ohio. 13 Q. Have you ever prescribed opioid 14 medications? 15 A. Yes. 16 Q. Since when? 17 A. I prescribe opioid medications 18 on a weekly basis. 19 Q. So when did you start 20 prescribing opioid medications? 21 A. Since I obtained a DEA license. 22 Q. And when was that? 23 A. That was in 2000, 2001. 24 Q. Approximately how many patients 25 do you believe you've prescribed opioid</p>

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<p>1 medications to?</p> <p>2 A. It's difficult for me to put a</p> <p>3 number on that. I've been prescribing opioid</p> <p>4 medications since I became a practicing</p> <p>5 physician, and in recent years, I prescribed</p> <p>6 more opioid medication in the treatment of</p> <p>7 opioid use disorder.</p> <p>8 Q. Other than opioid use disorder,</p> <p>9 have you prescribed opioid medications for</p> <p>10 any other condition or indication?</p> <p>11 A. Yes, I have. In the general</p> <p>12 practice of medicine through my career, I</p> <p>13 have prescribed other opioid medications.</p> <p>14 Q. What conditions or indications?</p> <p>15 A. Typically pain conditions.</p> <p>16 Q. When you prescribe opioid</p> <p>17 medications to your patients, do you weigh</p> <p>18 the risks and benefits based on your</p> <p>19 individual patients' medical histories and</p> <p>20 conditions?</p> <p>21 A. Yes, of course.</p> <p>22 Q. Do you have any degrees in</p> <p>23 epidemiology?</p> <p>24 A. No.</p> <p>25 Q. Can you explain to the jury</p>	<p>1 Q. Okay. Other than the Medicare</p> <p>2 database, did you conduct any of your own</p> <p>3 epidemiological analysis of any data in this</p> <p>4 case specific to the -- strike that.</p> <p>5 Other than the Medicare</p> <p>6 database, did you conduct any original</p> <p>7 epidemiological analysis of any data in this</p> <p>8 case?</p> <p>9 A. Yes, I did.</p> <p>10 Q. What data?</p> <p>11 A. Qualitative data that I</p> <p>12 collected in preparation for writing my book,</p> <p>13 "Drug Dealer, MD: How Doctors Were Duped,</p> <p>14 Patients Got Hooked, and Why It's So Hard to</p> <p>15 Stop."</p> <p>16 Q. And what do you mean by</p> <p>17 qualitative data in connection with writing</p> <p>18 your book?</p> <p>19 A. Interviews that I conducted</p> <p>20 with patients and health care providers in an</p> <p>21 attempt to understand the progression of the</p> <p>22 opioid epidemic in our population.</p> <p>23 Q. Okay. And other than</p> <p>24 conducting interviews in connection with</p> <p>25 writing your book, did you conduct any</p>
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<p>1 what epidemiology means?</p> <p>2 A. Epidemiology is the study of</p> <p>3 the progression of disease through a</p> <p>4 population.</p> <p>5 Q. Did you yourself actually</p> <p>6 conduct any of the epidemiological research</p> <p>7 cited in your report regarding factors</p> <p>8 associated with the opioid crisis?</p> <p>9 A. Yes, I did.</p> <p>10 Q. And can you explain what</p> <p>11 research you conducted?</p> <p>12 A. I conducted research regarding</p> <p>13 who was prescribing opioids in this country</p> <p>14 as well as who is prescribing buprenorphine</p> <p>15 for the treatment of opioid use disorder,</p> <p>16 which is relevant to the opioid epidemic more</p> <p>17 broadly.</p> <p>18 Q. And what was the information</p> <p>19 upon which you conducted your research?</p> <p>20 A. It was based on Medicare -- a</p> <p>21 Medicare database from 2013.</p> <p>22 Q. Did you calculate or formulate</p> <p>23 any of your own regression models or</p> <p>24 statistical analyses in this case?</p> <p>25 A. No, I did not.</p>	<p>1 quantitative analysis in connection with</p> <p>2 that?</p> <p>3 A. No.</p> <p>4 Q. If you were asked to design an</p> <p>5 epidemiological study and statistically</p> <p>6 analyze the data results for submission to a</p> <p>7 peer-reviewed journal, would you ask for</p> <p>8 help, or would you do that all by yourself?</p> <p>9 MR. ARBITBLIT: Objection.</p> <p>10 Compound.</p> <p>11 QUESTIONS BY MR. TSAI:</p> <p>12 Q. You can answer.</p> <p>13 A. So I don't hold myself out as a</p> <p>14 biostatistician. I work with others who have</p> <p>15 expertise in that area and together we</p> <p>16 collaboratively think about the important</p> <p>17 questions and interpret the data, so I would</p> <p>18 be intimately involved in that process, but I</p> <p>19 would not be conducting the statistical</p> <p>20 analysis by myself.</p> <p>21 Q. What is the total amount of</p> <p>22 peer-reviewed research studies or articles</p> <p>23 you've authored in the field of epidemiology?</p> <p>24 A. I feel like I answered that</p> <p>25 question before.</p>

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<p style="text-align: right;">Page 26</p> <p>1 working on the submission of any ANDA to the</p> <p>2 FDA?</p> <p>3 A. No.</p> <p>4 Q. What is an NDA?</p> <p>5 A. I don't know.</p> <p>6 Q. What is an ANDA?</p> <p>7 A. I don't know.</p> <p>8 Q. Have you ever worked on the</p> <p>9 submission -- do you have any experience</p> <p>10 working on the submission of any prescription</p> <p>11 medication marketing materials to the FDA for</p> <p>12 government approval?</p> <p>13 A. I served on the research</p> <p>14 advisory panel of California where we</p> <p>15 reviewed studies that were being conducted in</p> <p>16 the state of California on using various</p> <p>17 investigative pharmaceuticals and my role was</p> <p>18 to assess the safety of those studies. And</p> <p>19 so in that sense I have reviewed numerous</p> <p>20 studies in the process of companies seeking</p> <p>21 FDA approval for their drug.</p> <p>22 Q. And what was the connection in</p> <p>23 that panel to any company's marketing</p> <p>24 material?</p> <p>25 A. Well, it wasn't marketing</p>	<p style="text-align: right;">Page 28</p> <p>1 Counties, and so I can speak to the</p> <p>2 issue of the opioid epidemic in those</p> <p>3 counties.</p> <p>4 QUESTIONS BY MR. TSAI:</p> <p>5 Q. Is the CDC data that you are</p> <p>6 referring to specific to any particular</p> <p>7 individuals residing in those counties that</p> <p>8 allows you to identify their medical</p> <p>9 condition or the circumstances of their</p> <p>10 opioid use?</p> <p>11 MR. ARBITBLIT: Object to form.</p> <p>12 THE WITNESS: The CDC data is</p> <p>13 looking at individuals in aggregate,</p> <p>14 not any one individual that I could</p> <p>15 identify.</p> <p>16 QUESTIONS BY MR. TSAI:</p> <p>17 Q. Have you ever asked for or been</p> <p>18 provided any information specific to Cuyahoga</p> <p>19 or Summit Counties regarding individual</p> <p>20 persons whose addiction the counties contend</p> <p>21 led to costs in this case?</p> <p>22 MR. ARBITBLIT: I'll instruct</p> <p>23 you not to answer as to that question</p> <p>24 because it involves the</p> <p>25 attorney-expert privilege.</p>
<p style="text-align: right;">Page 27</p> <p>1 material, per se.</p> <p>2 Q. Do you have any experience</p> <p>3 regarding FDA regulations that govern</p> <p>4 pharmaceutical marketing?</p> <p>5 A. No.</p> <p>6 Q. Have you ever treated any</p> <p>7 person in Cuyahoga or Summit Counties for</p> <p>8 opioid addiction?</p> <p>9 A. No.</p> <p>10 Q. Have you ever treated any</p> <p>11 patients in Cuyahoga or Summit Counties for</p> <p>12 any medical condition related to opioids?</p> <p>13 A. No.</p> <p>14 Q. Have you ever been to Summit</p> <p>15 County?</p> <p>16 A. No, but I have been to Cuyahoga</p> <p>17 County.</p> <p>18 Q. Are you able to identify any</p> <p>19 particular individuals whose opioid addiction</p> <p>20 or overdose led to costs incurred by Cuyahoga</p> <p>21 or Summit Counties?</p> <p>22 MR. ARBITBLIT: Object to form.</p> <p>23 THE WITNESS: I am able to -- I</p> <p>24 have analyzed the CDC data from Ohio,</p> <p>25 including Summit and Cuyahoga</p>	<p style="text-align: right;">Page 29</p> <p>1 Don't answer.</p> <p>2 QUESTIONS BY MR. TSAI:</p> <p>3 Q. Let me rephrase it.</p> <p>4 Have you ever reviewed any</p> <p>5 information specific to Cuyahoga or Summit</p> <p>6 Counties regarding any actual individuals</p> <p>7 whose opioid addiction the counties contend</p> <p>8 led to the costs that they're seeking in this</p> <p>9 case?</p> <p>10 A. Well, I have reviewed</p> <p>11 information specific to Cuyahoga and Summit</p> <p>12 Counties regarding individuals living in</p> <p>13 those counties broadly speaking as an</p> <p>14 aggregate, not any one individual. I haven't</p> <p>15 personally treated any one individual living</p> <p>16 in those counties.</p> <p>17 Q. Well, let me ask it this way:</p> <p>18 Do you have any basis to tell us whether for</p> <p>19 any individual in Cuyahoga and Summit</p> <p>20 Counties whose opioid addiction or overdose</p> <p>21 allegedly led the counties to incur expenses,</p> <p>22 the clinical context of their opioid use?</p> <p>23 MR. ARBITBLIT: Object to form.</p> <p>24 THE WITNESS: Yes, I believe</p> <p>25 that I do.</p>

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<p style="text-align: right;">Page 46</p> <p>1 trying to capture the very real</p> <p>2 phenomenon of flooding in our society</p> <p>3 of opioid medication as a result of</p> <p>4 misleading messaging by the defendants</p> <p>5 that led to the use of those opioids</p> <p>6 in minor and chronic pain conditions</p> <p>7 and then made them readily accessible,</p> <p>8 not just to people who were prescribed</p> <p>9 opioids, but even those not being</p> <p>10 prescribed opioids.</p> <p>11 QUESTIONS BY MR. TSAI:</p> <p>12 Q. And to be clear about the scope</p> <p>13 of this phenomenon, as you call it, does the</p> <p>14 Tsunami Effect include within its scope</p> <p>15 individuals who deliberately committed a</p> <p>16 crime in obtaining and using opioids?</p> <p>17 MR. ARBITBLIT: Object to form.</p> <p>18 THE WITNESS: Yes.</p> <p>19 QUESTIONS BY MR. TSAI:</p> <p>20 Q. And just in going back to our</p> <p>21 discussion about your practice of prescribing</p> <p>22 opioid medications to your patients, can you</p> <p>23 name the opioid medications that you have</p> <p>24 prescribed over the course of your career?</p> <p>25 A. I have prescribed opioids,</p>	<p style="text-align: right;">Page 48</p> <p>1 what are you referring to?</p> <p>2 A. Well, I have a courtesy</p> <p>3 appointment at Stanford University School of</p> <p>4 Medicine in the department of pain. Those</p> <p>5 courtesy appointments are given out in</p> <p>6 recognition of my expertise in the treatment</p> <p>7 of pain. I see patients within the Stanford</p> <p>8 University School of Medicine Pain Clinic.</p> <p>9 In that context, I regularly collaborate with</p> <p>10 my pain colleagues around complex patients.</p> <p>11 We have interdisciplinary team treatment</p> <p>12 meetings where we will discuss those patients</p> <p>13 in collaboration to try to come together to</p> <p>14 find the best treatment plan.</p> <p>15 I also frequently communicate</p> <p>16 with my pain colleagues using the electronic</p> <p>17 medical records system and by telephone as we</p> <p>18 collaborate together to come up with the best</p> <p>19 treatment plan for our patients with pain.</p> <p>20 Q. Are there any particular</p> <p>21 branded opioid medications that you can</p> <p>22 recall prescribing?</p> <p>23 A. No.</p> <p>24 Q. Do you recall prescribing</p> <p>25 hydromorphone?</p>
<p style="text-align: right;">Page 47</p> <p>1 Schedule II opioids, over the course of my</p> <p>2 career, probably every one that you could</p> <p>3 imagine in the course of inpatient treatment.</p> <p>4 And I can't specifically name</p> <p>5 them because I can't recollect the specific</p> <p>6 instances.</p> <p>7 In recent years, especially</p> <p>8 practicing as an outpatient provider, I</p> <p>9 primarily prescribe buprenorphine-naloxone in</p> <p>10 the use of opioid use disorder.</p> <p>11 Q. Have you prescribed oxycodone?</p> <p>12 A. Not to my recollection in</p> <p>13 certain years. There may have been instances</p> <p>14 when I temporarily took over that</p> <p>15 prescription in the case of a patient that I</p> <p>16 inherited in an effort to help them taper off</p> <p>17 of that medication, but normally I would not</p> <p>18 do that.</p> <p>19 Normally I would collaborate</p> <p>20 with my pain colleague and advise them how to</p> <p>21 help that patient taper down to a safer dose</p> <p>22 or come off the medication, oxycodone, all</p> <p>23 together.</p> <p>24 Q. And when you refer to a pain</p> <p>25 colleague that you would collaborate with,</p>	<p style="text-align: right;">Page 49</p> <p>1 A. I think I already answered that</p> <p>2 question.</p> <p>3 Q. What was your answer? I don't</p> <p>4 recall.</p> <p>5 A. I don't recall any specific</p> <p>6 pain medications that I prescribed outside of</p> <p>7 the buprenorphine-naloxone that I now</p> <p>8 prescribe regularly in my outpatient</p> <p>9 practice.</p> <p>10 Q. Do you have any experience or</p> <p>11 expertise in regard to the prescription drug</p> <p>12 supply chain?</p> <p>13 MR. ARBITBLIT: Object to form.</p> <p>14 THE WITNESS: I am aware of the</p> <p>15 role of the distributors in this case.</p> <p>16 I have read the complaint. I do</p> <p>17 acknowledge their contribution to the</p> <p>18 opioid epidemic, in particular the</p> <p>19 flooding of pills in small towns that</p> <p>20 should have alerted them to a problem,</p> <p>21 which they did not take action on.</p> <p>22 MR. TSAI: Respectfully move to</p> <p>23 strike that answer.</p> <p>24 QUESTIONS BY MR. TSAI:</p> <p>25 Q. Have you ever worked for a</p>

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<p style="text-align: right;">Page 50</p> <p>1 pharmaceutical company or consulted for one?</p> <p>2 A. No.</p> <p>3 Q. Do you have any experience or</p> <p>4 expertise regarding the setting of DEA quotas</p> <p>5 for prescription opioid medications?</p> <p>6 A. I'm aware of DEA quotas. I'm</p> <p>7 aware of the discussion around them vis-à-vis</p> <p>8 the opioid epidemic.</p> <p>9 Q. Do you agree that the</p> <p>10 defendants in this case are part of the legal</p> <p>11 prescription medicine manufacturing and</p> <p>12 supply business?</p> <p>13 MR. ARBITBLIT: Object to form.</p> <p>14 THE WITNESS: I guess I'm</p> <p>15 not -- I don't really understand the</p> <p>16 question.</p> <p>17 QUESTIONS BY MR. TSAI:</p> <p>18 Q. The defendants in this case are</p> <p>19 making and selling legally approved,</p> <p>20 government-regulated medicines?</p> <p>21 MR. ARBITBLIT: Is that a</p> <p>22 question or a statement?</p> <p>23 QUESTIONS BY MR. TSAI:</p> <p>24 Q. Do you agree?</p> <p>25 A. Is that a question or a</p>	<p style="text-align: right;">Page 52</p> <p>1 phenomenon that you call the Tsunami Effect?</p> <p>2 MR. ARBITBLIT: Object to form.</p> <p>3 THE WITNESS: I guess I would</p> <p>4 want to know what multiple steps</p> <p>5 you're referring to.</p> <p>6 QUESTIONS BY MR. TSAI:</p> <p>7 Q. Well, as you envisioned the</p> <p>8 Tsunami Effect, do you agree that for any of</p> <p>9 the prescription opioid medications that you</p> <p>10 refer to in your report -- first, it has to</p> <p>11 be submitted for FDA approval?</p> <p>12 A. Yes.</p> <p>13 Q. And are you familiar with what</p> <p>14 requirements must be met in order for the</p> <p>15 government to approve a prescription opioid</p> <p>16 medication as safe and effective?</p> <p>17 A. I am familiar, but I have not</p> <p>18 been asked to opine on that aspect of the</p> <p>19 case.</p> <p>20 Q. And in addition to approval by</p> <p>21 the Food and Drug Administration as safe and</p> <p>22 effective, do you agree that opioid</p> <p>23 medications must be approved by the DEA for</p> <p>24 manufacturing and sale?</p> <p>25 A. Yes.</p>
<p style="text-align: right;">Page 51</p> <p>1 statement?</p> <p>2 Q. I said, do you agree with that?</p> <p>3 A. Could you rephrase the</p> <p>4 question?</p> <p>5 Q. The defendants in the case are</p> <p>6 making and selling legally approved,</p> <p>7 government-regulated medicines; is that</p> <p>8 correct?</p> <p>9 A. Well, I guess I would object to</p> <p>10 the form of the question, especially the</p> <p>11 government-regulated medicine part. I think</p> <p>12 that the defendants in this case have also</p> <p>13 had a major responsibility in that process of</p> <p>14 regulation.</p> <p>15 Q. Do you have any basis to say</p> <p>16 that defendants are selling medicines that</p> <p>17 are not legally approved?</p> <p>18 MR. ARBITBLIT: Object to form.</p> <p>19 THE WITNESS: Yes, the</p> <p>20 medicines are legally approved.</p> <p>21 QUESTIONS BY MR. TSAI:</p> <p>22 Q. Do you agree that there are</p> <p>23 multiple steps between a prescription opioid</p> <p>24 medication being approved by the government</p> <p>25 on the one hand and the effects, the</p>	<p style="text-align: right;">Page 53</p> <p>1 Q. Okay. And then once an opioid</p> <p>2 medication pill is made, what is your</p> <p>3 understanding of how it makes its way to an</p> <p>4 actual individual in Cuyahoga and Summit</p> <p>5 Counties for use?</p> <p>6 MR. ARBITBLIT: Object to form.</p> <p>7 THE WITNESS: Well, there's the</p> <p>8 production part, and then there's the</p> <p>9 distribution part where it's then</p> <p>10 transported to a pharmacy, and then</p> <p>11 the pharmacy is the dispensing agent</p> <p>12 for that pill.</p> <p>13 QUESTIONS BY MR. TSAI:</p> <p>14 Q. And before any individual in</p> <p>15 Cuyahoga and Summit Counties can obtain an</p> <p>16 opioid, they need to get a prescription from</p> <p>17 a doctor, correct?</p> <p>18 MR. ARBITBLIT: Object to form.</p> <p>19 THE WITNESS: Yes.</p> <p>20 QUESTIONS BY MR. TSAI:</p> <p>21 Q. Okay. So if we could discuss</p> <p>22 one of the articles that you cite in your</p> <p>23 study.</p> <p>24 MR. TSAI: Can we have Tab 3,</p> <p>25 the McCabe study?</p>

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<p>1 dentist, approximately 6 percent of</p> <p>2 them were later diagnosed with an</p> <p>3 opioid use disorder within a year.</p> <p>4 My point being that there is a</p> <p>5 risk with exposure to medical use of</p> <p>6 opioids, not just to nonmedical use of</p> <p>7 opioids.</p> <p>8 MR. ARBITBLIT: And Federal</p> <p>9 Rule 106, Rule of Completeness,</p> <p>10 Counsel, page 378 of the article</p> <p>11 you're reading from states exactly</p> <p>12 this, "Medical use of prescription</p> <p>13 opioids during adolescence is</p> <p>14 associated with greater odds of</p> <p>15 subsequent prescription opioid</p> <p>16 misuse," citing Harbaugh 2018, McCabe,</p> <p>17 2013, and '16, and Mlech, 2015.</p> <p>18 MR. TSAI: I object to</p> <p>19 counsel's testimony.</p> <p>20 MR. ARBITBLIT: It's not</p> <p>21 testimony. It's the Rule of</p> <p>22 Completeness, Counsel. You should be</p> <p>23 familiar with it.</p> <p>24 MR. TSAI: The --</p> <p>25</p>	<p>1 who indicated medical use without a history</p> <p>2 of NMUPO did not differ from adolescents when</p> <p>3 no history of medical use of prescription</p> <p>4 opioids or NMUPO in the odds of substance use</p> <p>5 disorders?</p> <p>6 Can you tell the jury what that</p> <p>7 means, in your opinion?</p> <p>8 A. That means comparing the risk</p> <p>9 in those two populations, they had similar</p> <p>10 risk.</p> <p>11 Q. So I wanted to ask you --</p> <p>12 turning back to Exhibit 1, which is your</p> <p>13 report, on page 89, you talk about</p> <p>14 hepatitis C, HIV and other infectious</p> <p>15 diseases.</p> <p>16 Have you reviewed any data to</p> <p>17 reliably rule out the likelihood that cases</p> <p>18 of hepatitis C, HIV or other infectious</p> <p>19 diseases were caused by actions independent</p> <p>20 from opioid use?</p> <p>21 A. No.</p> <p>22 Q. And actions independent of</p> <p>23 opioid use that are associated or that cause</p> <p>24 infectious diseases like HIV and hepatitis C</p> <p>25 include risky sexual conduct, for example; do</p>
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<p>1 QUESTIONS BY MR. TSAI:</p> <p>2 Q. So putting aside absolute risk,</p> <p>3 and we'll talk about risk later on, but what</p> <p>4 is your -- this is a finding comparing</p> <p>5 likelihood of addictive substance use</p> <p>6 disorder in two groups, correct, adolescents</p> <p>7 who had medical use of prescription opioids,</p> <p>8 no history of nonmedical use or abuse, and</p> <p>9 adolescents who never took prescription</p> <p>10 opioids, correct?</p> <p>11 Am I reading that correct?</p> <p>12 MR. ARBITBLIT: Object to form.</p> <p>13 THE WITNESS: So to me, this --</p> <p>14 that statement that you just read is</p> <p>15 good evidence for the Tsunami Effect.</p> <p>16 That basically because there has been</p> <p>17 increased access to opioids, including</p> <p>18 for teenagers, that has subsequently</p> <p>19 increased their risk of going on to</p> <p>20 develop some kind of substance use</p> <p>21 problem.</p> <p>22 MR. TSAI: I move to strike.</p> <p>23 QUESTIONS BY MR. TSAI:</p> <p>24 Q. What is your -- what is the --</p> <p>25 the meaning of the finding that adolescents</p>	<p>1 you agree?</p> <p>2 A. Yes.</p> <p>3 Q. Have you reviewed any data to</p> <p>4 reliably rule out the likelihood that cases</p> <p>5 of hepatitis C, HIV or other infectious</p> <p>6 diseases you refer to existed prior to any</p> <p>7 opioid addiction or opioid abuse?</p> <p>8 A. No.</p> <p>9 Q. Do you have any -- did you</p> <p>10 conduct any analysis, or do you have any</p> <p>11 basis to quantify what percentage of cases of</p> <p>12 hepatitis C, HIV and other infectious</p> <p>13 diseases that you refer to were caused by</p> <p>14 reasons that had nothing to do with opioid</p> <p>15 use?</p> <p>16 A. No.</p> <p>17 Q. And just to be clear, opioid</p> <p>18 use disorder and addiction are not</p> <p>19 contagious, infectious diseases, correct?</p> <p>20 A. I would sort of disagree with</p> <p>21 that.</p> <p>22 Q. Is there a pathogen? Is there</p> <p>23 an opioid use pathogen?</p> <p>24 MR. ARBITBLIT: Let her finish</p> <p>25 her answer.</p>

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<p>1 THE WITNESS: There is not a 2 pathogen, per se, but the way that 3 opioid use disorder has spread through 4 the population is quite similar in 5 pattern to the way that infectious 6 diseases spread through close 7 contacts. 8 QUESTIONS BY MR. TSAI: 9 Q. If I touch someone who has 10 opioid use disorder, do I get opioid use 11 disorder? 12 A. No, but you also don't get HIV. 13 Q. If I receive a blood 14 transfusion from someone with opioid use 15 disorder, do I get opioid use disorder? 16 A. No. 17 MR. ARBITBLIT: Counsel, we've 18 been going just a over an hour. 19 Is it time for a little break? 20 MR. TSAI: Sure. Off the 21 record, please. 22 VIDEOGRAPHER: We're going off 23 the record, and the time is 9:11 a.m. 24 (Off the record at 9:11 a.m.) 25 VIDEOGRAPHER: We are now going</p>	<p>1 Effect," capital D, capital E, and there you 2 refer to individuals who become dependent on 3 opioids independent of addiction. 4 That's how you defined 5 Dependence Effect. 6 What is opioid dependence, in 7 your words, independent of addiction? What 8 does that mean? 9 A. So that distinction has become 10 important with the new criteria for 11 diagnosing a substance use disorder with the 12 DSM-V, which -- the DSM-V was a departure 13 from the DSM-IV in the sense that prior to 14 the DSM-V, the criteria of physiologic 15 tolerance and withdrawal counted toward a 16 diagnosis of addiction. 17 But with the evolution to the 18 DSM-V, that no longer counted under the 19 specific circumstances of a patient receiving 20 an opioid from a medical doctor and 21 developing tolerance and withdrawal as a 22 result of taking that medication, that 23 opioid, under a prescription as prescribed, 24 which de facto made it more difficult, 25 created a higher threshold, essentially, for</p>
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<p>1 back on the record, and the time is 2 9:23 a.m. 3 QUESTIONS BY MR. TSAI: 4 Q. And just one quick note: In 5 most depositions, we don't have this handy 6 LiveNote screen, and I've noticed that you've 7 been hearing my questions but also reading. 8 If I could ask you just to 9 listen to my questions. If you need 10 clarification, you can certainly look, but 11 this does -- if you kind of double up, it 12 does take up more time. 13 MR. ARBITBLIT: I'll instruct 14 you to pay no attention to that. You 15 look at the screen. The questions are 16 complex. It's serious litigation. 17 Do what you need to do to 18 understand the question. 19 QUESTIONS BY MR. TSAI: 20 Q. So -- 21 MR. ARBITBLIT: That's why the 22 screen's here. 23 QUESTIONS BY MR. TSAI: 24 Q. -- let me turn to the second 25 capitalized term in your report, "Dependence</p>	<p>1 diagnosing addiction with the DSM-V, but was 2 a way of recognizing that the physiologic 3 adaptation to opioids occurs to patients 4 taking opioids with a medical -- with a 5 medical prescription. 6 And so the DSM-V was an attempt 7 to distinguish between those individuals who 8 developed physiologic dependence under the 9 care of a doctor versus those individuals who 10 developed physiologic dependence, probably 11 also in many instances under the care of a 12 doctor, but also had these other behavioral 13 components that we use to signify the problem 14 of addiction. 15 Does that answer your question? 16 Q. So do you agree with the 17 changes that were implemented in DSM-V's 18 diagnostic criteria for opioid use disorder? 19 A. I accept those changes. I 20 think that those -- that the physiologic 21 dependence, so the neurobiological changes 22 that occur in the brain as a result of 23 physical dependence on the opioid, can't be 24 distinguished necessarily from the 25 neurobiological changes that happen in the</p>

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<p style="text-align: right;">Page 74</p> <p>1 QUESTIONS BY MR. TSAI:</p> <p>2 Q. And discontinuation phenomenon,</p> <p>3 that is, when a person using an</p> <p>4 antidepressant is going off of it, is</p> <p>5 tapering off or down?</p> <p>6 A. That's right.</p> <p>7 Q. And they experience withdrawal?</p> <p>8 MR. ARBITBLIT: Object to form.</p> <p>9 THE WITNESS: They experience</p> <p>10 some physical symptoms associated with</p> <p>11 that taper process.</p> <p>12 QUESTIONS BY MR. TSAI:</p> <p>13 Q. So am I right that</p> <p>14 individuals -- some individuals classified as</p> <p>15 having an opioid use disorder under the prior</p> <p>16 DSM-IV framework would not be deemed to have</p> <p>17 an opioid use disorder under the current</p> <p>18 updated definition?</p> <p>19 A. That's correct.</p> <p>20 Q. Okay. And so in tying your</p> <p>21 Dependence Effect phenomenon to dependence as</p> <p>22 opposed to addiction, that's a broader net;</p> <p>23 am I right?</p> <p>24 A. Yes.</p> <p>25 Q. It's more permissive?</p>	<p style="text-align: right;">Page 76</p> <p>1 dependence?</p> <p>2 MR. ARBITBLIT: Object to form.</p> <p>3 THE WITNESS: Almost always,</p> <p>4 yes.</p> <p>5 QUESTIONS BY MR. TSAI:</p> <p>6 Q. Does it inevitably lead to</p> <p>7 dependence?</p> <p>8 A. In the vast majority of cases,</p> <p>9 yes.</p> <p>10 Q. Does it immediately and</p> <p>11 automatically lead to dependence?</p> <p>12 MR. ARBITBLIT: Object to form.</p> <p>13 THE WITNESS: Not immediately.</p> <p>14 It takes people varying degrees of</p> <p>15 time. Some people become dependent</p> <p>16 within a matter of days to weeks.</p> <p>17 Other people can go much</p> <p>18 longer, but in the vast majority of</p> <p>19 cases, people who take opioids daily</p> <p>20 for an extended period of time become</p> <p>21 physically dependent on those opioids,</p> <p>22 such that they need more and more to</p> <p>23 get the same effect. And when they</p> <p>24 reduce their dose or stop taking them</p> <p>25 for some reason, they experience</p>
<p style="text-align: right;">Page 75</p> <p>1 MR. ARBITBLIT: Object to form.</p> <p>2 THE WITNESS: What do you mean</p> <p>3 by "permissive"?</p> <p>4 QUESTIONS BY MR. TSAI:</p> <p>5 Q. Well, you said lower bar, upper</p> <p>6 bar.</p> <p>7 So let me get -- it's a lower</p> <p>8 bar to be considered dependent in your view</p> <p>9 as opposed to addicted?</p> <p>10 A. I would say the criteria are</p> <p>11 different. I don't think I would use lower</p> <p>12 bar versus higher bar. They're now</p> <p>13 categorized as distinct and separate</p> <p>14 phenomenon.</p> <p>15 The point of describing the</p> <p>16 Dependence Effect is to communicate that</p> <p>17 there are more than 10 million people in this</p> <p>18 country who have taken opioids as prescribed</p> <p>19 and become physically dependent and that</p> <p>20 that's a very serious and morbid physical</p> <p>21 condition, that being dependent on opioids is</p> <p>22 not some kind of benign or easily reversible</p> <p>23 phenomenon.</p> <p>24 Q. Does prescribing or dispensing</p> <p>25 of opioid medications always lead to</p>	<p style="text-align: right;">Page 77</p> <p>1 withdrawal.</p> <p>2 And in many cases the</p> <p>3 withdrawal is excruciating and very</p> <p>4 debilitating.</p> <p>5 QUESTIONS BY MR. TSAI:</p> <p>6 Q. Have you reviewed any</p> <p>7 information or conducted any analysis to</p> <p>8 quantify what individuals in the counties,</p> <p>9 Cuyahoga and Summit Counties, became opioid</p> <p>10 dependent?</p> <p>11 MR. ARBITBLIT: Object to form.</p> <p>12 THE WITNESS: Is this getting</p> <p>13 back to what we talked about before,</p> <p>14 this question?</p> <p>15 QUESTIONS BY MR. TSAI:</p> <p>16 Q. I don't think I asked about</p> <p>17 opioid dependence.</p> <p>18 A. Okay. Can you say the question</p> <p>19 again?</p> <p>20 Q. Have you reviewed any</p> <p>21 information or conducted any analysis to</p> <p>22 quantify what individuals in the counties,</p> <p>23 Cuyahoga and Summit Counties, became opioid</p> <p>24 dependent?</p> <p>25 MR. ARBITBLIT: Object to form.</p>

20 (Pages 74 to 77)

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<p style="text-align: right;">Page 78</p> <p>1 THE WITNESS: No. No. 2 QUESTIONS BY MR. TSAI: 3 Q. Can the Dependence Effect 4 phenomenon predict what individuals in what 5 particular cities or counties will become 6 addicted to or overdose from opioids? 7 A. Yes. 8 Q. How so? 9 A. People who are dependent on 10 opioids are at increased risk to suffer from 11 overdose from those opioids, even separate 12 from being diagnosed from opioids, and I can 13 explain that physiology, if you would like. 14 It's also true that people who 15 are opioid dependent are at very high risk to 16 go on to meet DSM-V criteria for opioid 17 addiction. 18 Q. Well, let me ask it from this 19 angle. 20 Have you ever tested the 21 Dependence Effect phenomenon to, for example, 22 rule out the inclusion of individuals who 23 deliberately committed a crime in obtaining 24 and using opioids? 25 MR. ARBITBLIT: Object to form.</p>	<p style="text-align: right;">Page 80</p> <p>1 A. Yes. 2 Q. Okay. Does the Dependence 3 Effect include within its scope individuals 4 who deliberately misused an opioid medication 5 knowing that they were not using it for its 6 intended indication; for example, crushing 7 it, snorting it for a high, for euphoria, 8 instead of to treat an indicated pain 9 condition? 10 A. Yes. 11 Q. So the third of your triagrid 12 {phonetic} is the Gateway Effect, capital G, 13 capital E. 14 So in -- on page 86 of your 15 report, Exhibit 1, you describe the Gateway 16 Effect as -- you say, "The trajectory to 17 addiction begins with exposure." Is that 18 right? 19 A. That's right. 20 Q. Okay. So have you ever 21 tested -- well -- actually, strike that. 22 I wanted to ask one more 23 question about the Dependence Effect. 24 Have you ever published the 25 theory of the Dependence Effect in any</p>
<p style="text-align: right;">Page 79</p> <p>1 THE WITNESS: I don't 2 understand your question. 3 QUESTIONS BY MR. TSAI: 4 Q. Have you ever tested the 5 Dependence Effect phenomenon -- well, let me 6 ask it this way. 7 Does the Dependence Effect 8 include within its scope individuals who 9 deliberately committed a crime in obtaining 10 and using opioids? 11 MR. ARBITBLIT: Object to form. 12 THE WITNESS: Yes. 13 QUESTIONS BY MR. TSAI: 14 Q. Does the Dependence Effect 15 include within its scope individuals who 16 deliberately misused a prescription opioid 17 medication knowing that medication was not 18 prescribed to him or her? 19 A. The Dependence Effect would 20 include anybody who has become 21 physiologically dependent on opioids. 22 Q. And that would include 23 individuals residing in Cuyahoga and Summit 24 Counties whose exposure to opioids was via 25 opioids that were not prescribed to them?</p>	<p style="text-align: right;">Page 81</p> <p>1 peer-reviewed, scientific journal? 2 A. I haven't -- I haven't -- I 3 haven't specifically used that terminology, 4 but in the JAMA article that we published on 5 buprenorphine prescribing, we do talk about 6 the exposure and the millions of people 7 exposed to opioids through a medical 8 prescription, the vast majority of whom 9 probably are opioid dependent. 10 Q. And have you specifically used 11 the terminology of the Tsunami Effect, 12 capital T, capital E, in any peer-reviewed 13 scientific journal? 14 A. No. 15 Q. Have you ever tested the 16 Gateway Effect, going to the third leg, to 17 quantify what percentage of persons 18 ultimately addicted to illegal heroin, or 19 fentanyl, were individuals who started out 20 purely with no substance abuse history and 21 whose initial exposure was via a medically 22 appropriate prescription of an opioid 23 medication? 24 MR. ARBITBLIT: Object to form. 25 THE WITNESS: Are you asking me</p>

<p style="text-align: right;">Page 82</p> <p>1 if I've personally done that 2 quantitative research? 3 QUESTIONS BY MR. TSAI: 4 Q. Yes. 5 A. I have not. 6 Q. Have you ever used the specific 7 terminology of the Gateway Effect and 8 published that observation in any 9 peer-reviewed scientific journal? 10 A. No. 11 Q. Have you ever tested the 12 Gateway Effect phenomenon to rule out the 13 inclusion of individuals who deliberately 14 committed a crime in obtaining and using 15 opioids? 16 A. I wouldn't rule out those 17 individuals. 18 Q. Okay. So the Gateway Effect, 19 as you envision it, as you define it, does 20 include within its scope persons, including 21 persons in Cuyahoga and Summit County, who 22 deliberately committed a crime in obtaining 23 and using opioids? 24 A. Yes. 25 Q. Does the Gateway Effect include</p>	<p style="text-align: right;">Page 84</p> <p>1 through that medical prescription, as 2 distinct from the Tsunami Effect, which is 3 those individuals who -- which includes those 4 individuals who used an opioid not 5 necessarily prescribed to them. 6 Q. Okay. So the -- you know, the 7 beginning bound of the set of individuals 8 that you define as within the Gateway Effect 9 are those individuals who received a 10 prescription directly from a doctor? 11 A. Yes, and thank you for allowing 12 me the opportunity to clarify that. 13 Q. So the Gateway theory posits a 14 particular direction of events: First, 15 prescription opioids prescribed by a doctor, 16 and then later illegal heroin or street 17 fentanyl addiction; is that right? 18 A. Not necessarily. 19 So that individual -- so you're 20 right in the sense that it posits an 21 individual who began with a prescription of 22 an opioid from a doctor, but it -- and it 23 could include those individuals who then turn 24 to illicit sources of heroin, but it also 25 includes those individuals who become</p>
<p style="text-align: right;">Page 83</p> <p>1 within its scope individuals who deliberately 2 misused a prescription opioid medication 3 knowing that medication was not prescribed to 4 them? 5 A. Yes. 6 Q. Does the Gateway Effect include 7 within its scope individuals who deliberately 8 misused a prescription opioid medication 9 knowing it -- knowing that they were using it 10 contrary to its intended indication and 11 approved indication, for example, to get a 12 high instead of treating pain? 13 A. So I would like to go back and 14 amend what I said previously about the 15 Gateway Effect and refer to my report, which 16 on page 86, specifically says that the 17 Gateway Effect describes those individuals 18 who became exposed and addicted, including 19 individuals who turned from prescription 20 opioids to illicit sources of opioids such as 21 heroin. 22 So what I'm -- the group I'm 23 referring to in the Gateway Effect is, in 24 fact, those individuals who started with a 25 medical prescription and then became addicted</p>	<p style="text-align: right;">Page 85</p> <p>1 addicted in an ongoing matter -- manner using 2 the opioids prescribed by that doctor. 3 Q. Have you ever tested whether 4 the Gateway Effect is confounded by 5 individuals who had already used heroin 6 before prescription opioid medications? 7 MR. ARBITBLIT: Object to form. 8 THE WITNESS: Well, that's 9 something that the McCabe article 10 looked at, and I think one of the 11 salient findings there is it's really 12 the combined effect of access to 13 nonmedical opioids, plus medical use, 14 that confers risk. It's not one or 15 the other in isolation, and both of 16 those individual groups can become 17 addicted. 18 So people can get addicted 19 entirely through a medical 20 prescription and not engage in 21 nonmedical use. They can engage in 22 nonmedical use and then also be 23 exposed medically; thus compounding 24 their risk. 25</p>

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<p style="text-align: right;">Page 86</p> <p>1 QUESTIONS BY MR. TSAI:</p> <p>2 Q. So you would rely on the McCabe</p> <p>3 study's findings in regard to those groups</p> <p>4 that you mentioned?</p> <p>5 MR. ARBITBLIT: Object to form.</p> <p>6 THE WITNESS: No, I'm not</p> <p>7 relying on the McCabe study findings.</p> <p>8 As I said before, I've done my own</p> <p>9 qualitative research, and I've also --</p> <p>10 I have vast experiential knowledge of</p> <p>11 this problem from the many patients</p> <p>12 I've treated in almost, you know, two</p> <p>13 decades.</p> <p>14 So I have seen the pattern of</p> <p>15 opioid addiction as it has occurred in</p> <p>16 those individuals.</p> <p>17 QUESTIONS BY MR. TSAI:</p> <p>18 Q. Does the Gateway Effect include</p> <p>19 within its scope individuals who had first</p> <p>20 used heroin before they used prescription</p> <p>21 opioids?</p> <p>22 A. No.</p> <p>23 Q. And how would you know for a</p> <p>24 particular person in Cuyahoga or Summit</p> <p>25 County with opioid use disorder that medical</p>	<p style="text-align: right;">Page 88</p> <p>1 So, for example, I've had many</p> <p>2 patients who were in recovery from an</p> <p>3 addiction to something else, who then got</p> <p>4 exposed to an opioid through a medical</p> <p>5 prescription and became addicted to that</p> <p>6 opioid or relapsed to their other substance</p> <p>7 who otherwise, I believe, would not have done</p> <p>8 so were it not for the unnecessary exposure</p> <p>9 to that opioid through a medical</p> <p>10 prescription.</p> <p>11 Q. And individuals with a history</p> <p>12 of substance abuse, and certainly a history</p> <p>13 of diagnosed substance use disorder, are at a</p> <p>14 higher risk of substance abuse disorder; do</p> <p>15 you agree?</p> <p>16 MR. ARBITBLIT: Object to form.</p> <p>17 THE WITNESS: We do know based</p> <p>18 on retrospective, epidemiologic</p> <p>19 studies that patients with a personal</p> <p>20 history of substance use disorder are</p> <p>21 at increased risk to develop an opioid</p> <p>22 addiction through a medical</p> <p>23 prescription of opioids, yes.</p> <p>24 QUESTIONS BY MR. TSAI:</p> <p>25 Q. So you would agree that for</p>
<p style="text-align: right;">Page 87</p> <p>1 history, that sequence?</p> <p>2 MR. ARBITBLIT: Object to form.</p> <p>3 THE WITNESS: There are good</p> <p>4 national data that have surveyed</p> <p>5 individuals asking them about which --</p> <p>6 individuals who have become addicted</p> <p>7 to opioids, asking them which opioid</p> <p>8 they started with, and over 80 percent</p> <p>9 of individuals report that they</p> <p>10 started with a prescription opioid.</p> <p>11 QUESTIONS BY MR. TSAI:</p> <p>12 Q. And those -- that statistic</p> <p>13 includes nonmedical use of prescription</p> <p>14 opioids?</p> <p>15 A. Yes, it does, but it also</p> <p>16 includes medical use of prescription opioids.</p> <p>17 Q. Have you ever tested whether</p> <p>18 the Gateway Effect is confounded by</p> <p>19 individuals who had already deliberately</p> <p>20 misused or abused other drugs before any</p> <p>21 medical opioid prescription?</p> <p>22 A. There are those cases, and I</p> <p>23 have treated those individuals, and to me</p> <p>24 that doesn't mitigate the problem of</p> <p>25 addiction through an opioid prescription.</p>	<p style="text-align: right;">Page 89</p> <p>1 individuals who reside in Cuyahoga and Summit</p> <p>2 County with opioid use disorder, an important</p> <p>3 piece of information to know is their history</p> <p>4 of substance abuse disorder and substance use</p> <p>5 history?</p> <p>6 MR. ARBITBLIT: Object to form.</p> <p>7 THE WITNESS: I don't really</p> <p>8 consider that that important a piece</p> <p>9 of history.</p> <p>10 QUESTIONS BY MR. TSAI:</p> <p>11 Q. So despite testifying that</p> <p>12 epidemiology shows that patients with a</p> <p>13 personal history of substance use disorder</p> <p>14 are at an increased risk to develop an opioid</p> <p>15 addiction through a medical prescription of</p> <p>16 opioids, you wouldn't want to know whether</p> <p>17 any particular individual in Cuyahoga and</p> <p>18 Summit Counties had such a personal history</p> <p>19 of substance abuse disorder?</p> <p>20 MR. ARBITBLIT: Object to form.</p> <p>21 Argumentative.</p> <p>22 THE WITNESS: To me what's much</p> <p>23 more relevant is that they're</p> <p>24 currently addicted to opioids. I</p> <p>25 don't consider their past history to</p>

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<p>1 inform that problem. 2 Furthermore, we know that many 3 people without a past history of 4 addiction can get addicted to opioids 5 through a doctor's prescription. 6 QUESTIONS BY MR. TSAI: 7 Q. Okay. And since your opinion 8 isn't -- individual's personal history of 9 substance use disorder is not information 10 that you would need to know, you did not 11 review any such information for any actual 12 individual with opioid use disorder in 13 Cuyahoga and Summit County; am I right? 14 MR. ARBITBLIT: Object to form. 15 Object to the preface. 16 THE WITNESS: I did not review 17 any individual patient's history. 18 QUESTIONS BY MR. TSAI: 19 Q. So based upon your clinical 20 experience, can you walk us through the steps 21 between a person receiving a prescription 22 from a doctor for an opioid medication and 23 the ultimate outcome of going out to a street 24 dealer and seeking illegal, nonprescribed, 25 nonregulated heroin or fentanyl?</p>	<p>1 the dose over time as that patient 2 inevitably develops tolerance. 3 That doctor, furthermore, 4 having been misled by the defendants 5 to believe that no dose is too high, 6 will continue to escalate that dose 7 over months to years until that 8 patient is at dangerously high doses 9 of opioids and at risk for all kinds 10 of morbidity and mortality, including 11 the risk of addiction. 12 And eventually that individual, 13 who is on very high doses of opioids, 14 has neurologic changes in their brain 15 such that if they -- they begin to 16 experience withdrawal often between 17 doses, so intradose withdrawal. 18 They have the sensation that 19 was validated by their doctor, but 20 which is probably not the case, that 21 the -- they need the opioids to treat 22 their pain when, in fact, taking the 23 opioids is most likely just treating 24 withdrawal from the last dose, but the 25 physiology and the pain of withdrawal</p>
Page 91	Page 93
<p>1 How does that -- how does the 2 Gateway Effect play out in your mind from 3 prescription to going out into a street 4 dealer? 5 MR. ARBITBLIT: Object to form. 6 Vague. Compound. 7 THE WITNESS: An individual 8 presents in a medical clinic with pain 9 and is prescribed opioids by that 10 doctor. 11 The doctor has been misled by 12 false promotional statements on the 13 part of defendants to believe that 14 there are benefits to the use of 15 opioids used long term in the 16 treatment of pain, despite the absence 17 of evidence for that. And that doctor 18 has also been told that the risks are 19 very small for addiction as long as 20 that individual is being prescribed 21 opioids for a pain condition. 22 So that well-intentioned and 23 compassionate doctor, who is trying to 24 do the right thing, will continue that 25 opioid prescription and even increase</p>	<p>1 drives that individual to then become 2 very preoccupied with their pain, very 3 preoccupied with the opioids, spending 4 more and more time at the doctor's 5 office with pain complaints, reporting 6 that the opioids are no longer 7 working, because they don't work in 8 most cases for chronic pain. 9 And again, the compassionate 10 doctor, being told that no dose is too 11 high, continues to escalate until that 12 individual is at a very, very high 13 dose, and that individual spends 14 almost all of their time possibly 15 going to the emergency room to try to 16 get more opioids to help with their 17 worsened pain and their withdrawal and 18 their tolerance, to the point that 19 that individual has developed a 20 full-blown opioid addiction within the 21 context of medical care. 22 Now, should it happen that at 23 some point that doctor retires or that 24 doctor gets ill and can't treat that 25 person anymore or that individual</p>

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<p>1 do not walk through the gateway to illegal 2 heroin? 3 MR. ARBITBLIT: Object to form. 4 QUESTIONS BY MR. TSAI: 5 Q. They turn away or otherwise 6 take another path? 7 A. That is what it says here, yes. 8 Q. Okay. So then going back to 9 page 1, the first page of the Muhuri article, 10 in the introduction section, if you look down 11 to the second paragraph, the authors observe 12 that this progression from opioid -- 13 prescription opioid medications to illegal 14 heroin may result simply because heroin may 15 be cheaper or easier for them to get in some 16 locations. 17 Do you see that? 18 A. Is that here on this first 19 page? 20 Q. Yeah. It's the first page -- 21 I'm sorry, I have a different -- right. 22 Sorry. 23 It is the second page of your 24 exhibit. The Bates number ends in 6028, and 25 it's the first full paragraph on that page.</p>	<p>1 I don't want to do this to 2 cause animosity. I do think, based on 3 my own experience and the rule itself, 4 that anything that in fairness should 5 be read with the same document as 6 you've brought in to evidence should 7 be read, and that's what the Rule of 8 Completeness, Federal Rule 106 says. 9 If you have something that you 10 think specifically overrules that rule 11 in our deposition protocol, please let 12 me know what it is. Otherwise, I'm 13 going to do it again, and I don't want 14 to do it again and have a fight with 15 you. That's not my purpose. 16 MR. TSAI: We have a limited 17 time on the record. Suffice it to 18 say, I disagree. 19 MR. ARBITBLIT: You can 20 disagree, and you can reserve your 21 rights, but I'm just going to read one 22 sentence from the same Muhuri article 23 that says, "There are many plausible 24 explanations for this finding, 25 including the Gateway theory of drug</p>
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<p>1 It says, "This progression may result simply 2 because heroin may be cheaper or easier for 3 them to get in some locations." 4 Do you see that? 5 A. Yes. 6 Q. Okay. Do you have any -- did 7 you review any information or do any analysis 8 to determine whether this reason for switched 9 to illegal heroin, that it's cheaper or 10 easier to get, whether that applied -- 11 applies in Cuyahoga or in Summit Counties? 12 A. No. 13 Q. Okay. 14 MR. TSAI: Could we get Tab 8, 15 please? 16 MR. ARBITBLIT: Okay. Counsel, 17 I don't want to have a disagreement 18 with you about this, but I don't see 19 in our summary of the protocol 20 anything that would overrule Federal 21 Rule 106. 22 If you have something that you 23 think prevents from me reading for the 24 Rule of Completeness, I would like to 25 know specifically what it is.</p>	<p>1 use, that posits that the use of some 2 drugs may expose individuals to a 3 repertoire of biological and 4 behavioral factors that could 5 influence their future use of other 6 drugs." 7 And that's at MDL_EXP_0006043, 8 and you can reserve whatever rights 9 you feel you have. But I'm trying to 10 do this expeditiously. I think I've 11 taken up a total of about two minutes 12 of your time. 13 MR. TSAI: And not only do I 14 reserve rights, I very much object to 15 counsel's eating up the time on the 16 record with his testimony and 17 colloquy, which is prohibited under 18 the deposition protocol expressly, so 19 I want to move on. 20 Can we get Tab 8, please? 21 (Lembke Exhibit 6 marked for 22 identification.) 23 QUESTIONS BY MR. TSAI: 24 Q. So I want to talk about the 25 Compton article that you cite in your report.</p>

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<p>1 MR. ARBITBLIT: Object to form.</p> <p>2 QUESTIONS BY MR. TSAI:</p> <p>3 Q. That relationship?</p> <p>4 A. I think that now I would say</p> <p>5 that my opinion has changed vis-à-vis this</p> <p>6 particular statement in the sense that this</p> <p>7 is a very general statement, that "the</p> <p>8 relationship between doctors' prescribing</p> <p>9 patterns and the initiation of heroin use</p> <p>10 remains unclear" because there's not a wealth</p> <p>11 of evidence I've reviewed showing there's a</p> <p>12 clear link between receiving an opioid</p> <p>13 prescription with a doctor and being at</p> <p>14 higher risk for progressing to heroin use.</p> <p>15 Q. And does that evidence include</p> <p>16 the studies that we went over just now, the</p> <p>17 NASEM, the Muhuri, the Compton?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. So going back to</p> <p>20 Compton -- do you have that article, the</p> <p>21 Compton article?</p> <p>22 A. Yeah.</p> <p>23 Q. If you could turn to page 156</p> <p>24 of that article.</p> <p>25 So in the left-hand column it's</p>	<p>1 than prescription opioids?</p> <p>2 A. I did not review individual</p> <p>3 cases.</p> <p>4 Q. Okay. And if we could turn to</p> <p>5 the next page, 157, of the Compton article,</p> <p>6 and the right-hand column, there they give</p> <p>7 statistics that compare heroin use to use of</p> <p>8 other substances.</p> <p>9 So am I reading this correctly,</p> <p>10 that heroin use over the period that was</p> <p>11 studied in the -- in this NEJM article also</p> <p>12 increased upon nonmedical users of</p> <p>13 stimulants?</p> <p>14 A. Yes, you're reading it</p> <p>15 correctly.</p> <p>16 Q. And what are examples of</p> <p>17 stimulants?</p> <p>18 A. Stimulants -- nicotine is a</p> <p>19 stimulant. Methamphetamine is a stimulant.</p> <p>20 Cocaine is a stimulant.</p> <p>21 Q. And during the same time</p> <p>22 period, heroin use also increased among users</p> <p>23 of tranquilizers, sedatives, cocaine,</p> <p>24 marijuana and alcohol, correct?</p> <p>25 A. Yes.</p>
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<p>1 above that heading "Break." The heading</p> <p>2 says, "Heroin use among people who use</p> <p>3 prescription opioids nonmedically."</p> <p>4 The sentence right before that,</p> <p>5 I'll read it, it says, "Finally, these</p> <p>6 differential properties and effects are</p> <p>7 likely to interact with interindividual</p> <p>8 variability in powerful complex and in</p> <p>9 completely predictable ways so that some</p> <p>10 persons who abuse prescription opioids could</p> <p>11 find heroin less rewarding than prescription</p> <p>12 opioids similarly rewarding or even more</p> <p>13 rewarding."</p> <p>14 Do you see that?</p> <p>15 A. Yes, I do.</p> <p>16 Q. And do you agree with that</p> <p>17 statement?</p> <p>18 A. I do.</p> <p>19 Q. All right. For any individuals</p> <p>20 in Cuyahoga and Summit Counties with opioid</p> <p>21 use disorder, did you review any information</p> <p>22 or have any other basis to say whether their,</p> <p>23 as the New England Journal of Medicine put</p> <p>24 it, individual variability was such that they</p> <p>25 found heroin less similarly or more rewarding</p>	<p>1 Q. Okay. And the next page, 158,</p> <p>2 if you look at this first full paragraph, the</p> <p>3 first sentence, the authors conclude that, "A</p> <p>4 key factor underlying the recent increases in</p> <p>5 rates of heroin use and overdose may be the</p> <p>6 low cost and high purity of heroin."</p> <p>7 Do you see that?</p> <p>8 A. I do.</p> <p>9 Q. And so am I reading that</p> <p>10 correctly that the finding is that for --</p> <p>11 when some persons who abuse prescription</p> <p>12 opioids then subsequently initiate heroin</p> <p>13 use, the cost and availability of heroin on</p> <p>14 the street are primary factors in that</p> <p>15 process?</p> <p>16 A. To me that statement needs to</p> <p>17 be put in the larger context of increased</p> <p>18 exposure to heroin through a medical</p> <p>19 prescription and subsequent development of</p> <p>20 opioid addiction to medical heroin --</p> <p>21 medical opioids, that then put all of those</p> <p>22 individuals at increased risk to progress to</p> <p>23 heroin use.</p> <p>24 So I think that that statement,</p> <p>25 as I read their intention, is that in the</p>

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<p style="text-align: right;">Page 166</p> <p>1 mood.</p> <p>2 QUESTIONS BY MR. TSAI:</p> <p>3 Q. And we're talking about</p> <p>4 co-occurring mental illness. Let's talk</p> <p>5 about past history of substance use disorder.</p> <p>6 Do you agree that past history</p> <p>7 of substance use disorder is a</p> <p>8 well-established risk factor for opioid use</p> <p>9 disorder?</p> <p>10 A. Yes.</p> <p>11 Q. And let me just give an</p> <p>12 example.</p> <p>13 Edlund found that about half of</p> <p>14 opioid overdose deaths involved another drug,</p> <p>15 most commonly benzodiazepines.</p> <p>16 Do you agree with that</p> <p>17 observation?</p> <p>18 MR. ARBITBLIT: Object to form.</p> <p>19 THE WITNESS: I agree that a</p> <p>20 large percentage of opioid overdose</p> <p>21 deaths involve another drug, commonly</p> <p>22 a sedative like a benzodiazepine.</p> <p>23 QUESTIONS BY MR. TSAI:</p> <p>24 Q. And can you give some examples</p> <p>25 of benzodiazepines?</p>	<p style="text-align: right;">Page 168</p> <p>1 Is that still your belief?</p> <p>2 A. Yes.</p> <p>3 Q. And have you done any work or</p> <p>4 analysis to quantify to what extent</p> <p>5 benzodiazepines are, as you say, a major</p> <p>6 culprit in the epidemic of prescription</p> <p>7 overdose deaths plaguing this country?</p> <p>8 A. So I published an article in</p> <p>9 the New England Journal of Medicine talking</p> <p>10 about the benzodiazepine problem. The</p> <p>11 article was not based on my own analysis, but</p> <p>12 was a review of published literature and some</p> <p>13 summative interpretations of how to</p> <p>14 intervene.</p> <p>15 And based on other</p> <p>16 publications, we found a seven-time increased</p> <p>17 mortality involved benzodiazepines between</p> <p>18 late 1990s and 2016, two-thirds of which also</p> <p>19 involved an opioid.</p> <p>20 Q. And did you, in connection with</p> <p>21 this article, dig into or quantify whether</p> <p>22 the benzodiazepine use occurred before or</p> <p>23 after the prescription opioid use?</p> <p>24 A. No.</p> <p>25 Q. So in your report on page 89,</p>
<p style="text-align: right;">Page 167</p> <p>1 A. Sure: Valium, Klonopin, Xanax,</p> <p>2 Ativan, Librium.</p> <p>3 Q. And you talk about a large</p> <p>4 percentage of opioid-related overdoses</p> <p>5 involve an individual that, to put it</p> <p>6 bluntly, has another addictive substance in</p> <p>7 their system.</p> <p>8 What do you mean by a large</p> <p>9 percentage? Can you be more specific?</p> <p>10 A. Two-thirds of deaths involving</p> <p>11 a benzodiazepine also involve an opioid</p> <p>12 prescription.</p> <p>13 Q. And if you could turn to your</p> <p>14 book, "Drug Dealer, MD," and page 146, the</p> <p>15 internal page number of your book, and the</p> <p>16 Bates number for that ends in 5680.</p> <p>17 A. Uh-huh.</p> <p>18 Q. It's the first full paragraph.</p> <p>19 It says, "Today, doctors' prescription for</p> <p>20 benzodiazepines continue to rise and are a</p> <p>21 major culprit in the epidemic of prescription</p> <p>22 overdose deaths plaguing this country.</p> <p>23 Nonetheless, benzodiazepines are relatively</p> <p>24 ignored in the national discussion on rising</p> <p>25 rates of addiction."</p>	<p style="text-align: right;">Page 169</p> <p>1 you say, "Economic downturn and the E-flux of</p> <p>2 manufacturing jobs in towns across America in</p> <p>3 the last 30 years have contributed to</p> <p>4 so-called deaths of despair, early mortality</p> <p>5 in middle-aged, non-Hispanic whites due</p> <p>6 primarily to drug overdose."</p> <p>7 Do you remember that passage?</p> <p>8 A. What page?</p> <p>9 Q. I believe it's page 89 of your</p> <p>10 report, Exhibit 1, subsection B, and you cite</p> <p>11 to the Case, Deaton study.</p> <p>12 Do you recall that?</p> <p>13 A. Yes.</p> <p>14 MR. TSAI: So can we get</p> <p>15 Tab 18?</p> <p>16 A. Oh, yeah. I found it.</p> <p>17 (Lembke Exhibit 8 marked for</p> <p>18 identification.)</p> <p>19 QUESTIONS BY MR. TSAI:</p> <p>20 Q. Okay. So if you could turn</p> <p>21 to -- the first page of the Case, Deaton</p> <p>22 article, this has a broad conclusion that</p> <p>23 "from 1999 to 2013, there was an increase in</p> <p>24 mortality among middle-aged, white,</p> <p>25 non-Hispanic Americans from all causes."</p>

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<p>1 Is that right?</p> <p>2 A. That's correct.</p> <p>3 Q. And in the introduction, the</p> <p>4 bold introductory section, this Case, Deaton</p> <p>5 study concluded that "these increased</p> <p>6 mortality was due to various factors,</p> <p>7 including drug and alcohol poisonings,</p> <p>8 suicide, chronic liver disease and</p> <p>9 cirrhosis."</p> <p>10 Is that right?</p> <p>11 A. Yes.</p> <p>12 Q. And second to the last -- just</p> <p>13 to be clear, do opioids cause deterioration</p> <p>14 or chronic liver disease or cirrhosis?</p> <p>15 A. Not typically.</p> <p>16 Q. Okay. And is it fair to say</p> <p>17 that those drivers of the increased mortality</p> <p>18 noted in the study were likely due to alcohol</p> <p>19 use disorder or alcoholism colloquially?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. And in your report, you</p> <p>22 acknowledge and agree that, quote/unquote,</p> <p>23 "economic disadvantage is a contributing</p> <p>24 factor to opioid-related mortality risk."</p> <p>25 Is that correct?</p>	<p>1 versus economic disadvantage.</p> <p>2 QUESTIONS BY MR. TSAI:</p> <p>3 Q. Have you in this case yourself</p> <p>4 done any work to rule out the likelihood that</p> <p>5 social and economic problems preexisting in</p> <p>6 the counties were an important contributing</p> <p>7 factor to observe opioid use disorder and</p> <p>8 mortality?</p> <p>9 MR. ARBITBLIT: Object to form.</p> <p>10 THE WITNESS: I have stated in</p> <p>11 my report that economic factors were a</p> <p>12 factor, but not the most important</p> <p>13 factor.</p> <p>14 The most important factor is</p> <p>15 the supply of opioids in that county.</p> <p>16 That is my opinion.</p> <p>17 QUESTIONS BY MR. TSAI:</p> <p>18 Q. And your opinion regarding the</p> <p>19 relative degree of contribution of social and</p> <p>20 economic problems, economic disadvantage,</p> <p>21 versus any conduct by the defendants, is that</p> <p>22 based on grappling with any county-specific</p> <p>23 data, or is it only based on the Ruhm study</p> <p>24 that you cited?</p> <p>25 MR. ARBITBLIT: Object to form.</p>
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<p>1 A. I would agree that it is one</p> <p>2 factor, but I also cited the Ruhm study,</p> <p>3 arguing that economic disadvantage</p> <p>4 contributes only 10 to 20 percent of</p> <p>5 mortality risk attributable to opioids,</p> <p>6 whereas the larger share of risk is due to</p> <p>7 the supply of opioids in a given geographic</p> <p>8 region.</p> <p>9 Q. Okay. And have you conducted</p> <p>10 any quantitative analysis of your own to</p> <p>11 quantify the specific contribution of</p> <p>12 economic disadvantage to opioid-related</p> <p>13 mortality risk?</p> <p>14 A. No.</p> <p>15 Q. Do you have a model or an</p> <p>16 analytical framework to untangle any costs</p> <p>17 related to any such preexisting social and</p> <p>18 economic problems versus any conduct by any</p> <p>19 defendant with respect to Cuyahoga and Summit</p> <p>20 Counties?</p> <p>21 MR. ARBITBLIT: Object to form.</p> <p>22 THE WITNESS: I think that the</p> <p>23 Ruhm study could be used to inform a</p> <p>24 model with respect to the risk</p> <p>25 incurred by the supply of opioids</p>	<p>1 THE WITNESS: It's based on my</p> <p>2 reading of the literature, not just</p> <p>3 this particular study, but also other</p> <p>4 studies showing that the amount of</p> <p>5 opioid prescribing in a given</p> <p>6 geographic region is the biggest</p> <p>7 predictor of opioid use disorder and</p> <p>8 opioid overdose in that region.</p> <p>9 MR. TSAI: Okay. Can we do tab</p> <p>10 27?</p> <p>11 (Lembke Exhibit 9 marked for</p> <p>12 identification.)</p> <p>13 QUESTIONS BY MR. TSAI:</p> <p>14 Q. So I would like to dig down</p> <p>15 into the actual ground floor circumstances of</p> <p>16 how folks get prescribed opioid medications.</p> <p>17 So do you recall that last year</p> <p>18 you gave a live interview on KQED with</p> <p>19 Michael Krasny for a program entitled</p> <p>20 "Medical Community Divided on Medicare's</p> <p>21 Policy to Shorten High-Dose Opioid</p> <p>22 Prescriptions"?</p> <p>23 A. Yes, I do.</p> <p>24 Q. Okay. And the exhibit that</p> <p>25 we've just put in front of you, does this</p>

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<p>1 appear to be a true and correct transcript of</p> <p>2 that interview that you participated in?</p> <p>3 A. Yes, it does.</p> <p>4 Q. Okay. And if you turn to</p> <p>5 page 8, they may have misspelled your name,</p> <p>6 but the Anna Lembke referred to, that's you?</p> <p>7 A. Which page?</p> <p>8 Q. It's page 8 of this exhibit.</p> <p>9 A. Yes.</p> <p>10 Q. Okay. So if you could turn to</p> <p>11 page 22 of the exhibit, and I'll start with</p> <p>12 line 2 of that page. I'll just read it.</p> <p>13 You stated --</p> <p>14 A. I'm sorry.</p> <p>15 Q. Oh, sure.</p> <p>16 A. I have two sets of page numbers</p> <p>17 here. Is this page 7, parentheses 22 to 25?</p> <p>18 Q. That's correct.</p> <p>19 A. Okay.</p> <p>20 Q. And it's split up into</p> <p>21 quadrants. So it's the left-hand quadrant,</p> <p>22 page 22.</p> <p>23 A. Yeah.</p> <p>24 Q. And you stated, "While it's a</p> <p>25 very complicated connection that I do address</p>	<p>1 role.</p> <p>2 Q. Okay. In your opinion -- is it</p> <p>3 still your opinion that certain individuals</p> <p>4 who have turned to disability payments are</p> <p>5 being forced to take certain types of</p> <p>6 medications to justify the sick role?</p> <p>7 A. So this is part of -- this is</p> <p>8 an excerpt from, as I state here, a much more</p> <p>9 complicated issue that I address more</p> <p>10 thoroughly in my book regarding how</p> <p>11 disability can sometimes consciously or</p> <p>12 otherwise encourage people living in poverty</p> <p>13 to adopt the sick role as a way to get</p> <p>14 disability payments.</p> <p>15 And in order to legitimize the</p> <p>16 sick role, they have to participate in that</p> <p>17 health care system, and in the '90s and early</p> <p>18 aughts and through today, it turns out</p> <p>19 participating in the health care system as a</p> <p>20 pain patient was actually dangerous because</p> <p>21 that -- the risk of being exposed</p> <p>22 unnecessarily to opioids was and continues to</p> <p>23 be very high, and exposure to opioids is one</p> <p>24 of the major risk factors for addiction.</p> <p>25 Q. So you use the term "forced to</p>
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<p>1 in my book, it's hard to kind of put it into</p> <p>2 a sound bite, but in general, you know,</p> <p>3 people who are suffering from poverty,</p> <p>4 unemployment, low education, are also people</p> <p>5 who are known to be at higher risk for</p> <p>6 addiction.</p> <p>7 "It's also true that this is a</p> <p>8 population that has turn towards disability</p> <p>9 payments as a way to make ends meet, and in</p> <p>10 order to, you know, justify the sick role and</p> <p>11 get disability payments. Many of these</p> <p>12 individuals have been forced to take certain</p> <p>13 type of medications because taking a</p> <p>14 medication can legitimize the sick role. So</p> <p>15 it's a complex web."</p> <p>16 Do you see that?</p> <p>17 A. Yes, I do.</p> <p>18 Q. What is "justifying the sick</p> <p>19 role"? What does that mean?</p> <p>20 A. Well, that's a term that goes</p> <p>21 back to Talcott Parsons, who identified</p> <p>22 social roles that people adopt, and anybody</p> <p>23 who participates in the health care system</p> <p>24 and views themselves as a, quote/unquote,</p> <p>25 patient is someone who has adopted the sick</p>	<p>1 take certain types of medications." Who in</p> <p>2 your opinion is forcing these individuals to</p> <p>3 take opioid medications to justify what</p> <p>4 you've called the sick role?</p> <p>5 MR. ARBITBLIT: Object to form.</p> <p>6 QUESTIONS BY MR. TSAI:</p> <p>7 Q. How does that mechanism work?</p> <p>8 A. The individuals are being</p> <p>9 forced by economic circumstance.</p> <p>10 Q. And this phenomenon of being</p> <p>11 forced by their individual economic</p> <p>12 circumstance to take certain medications to</p> <p>13 justify the sick role, have you reviewed any</p> <p>14 data specific to Cuyahoga or Summit Counties</p> <p>15 to determine whether that phenomenon occurred</p> <p>16 in the counties?</p> <p>17 A. Nationally we've seen a huge</p> <p>18 increase in the number of people going on to</p> <p>19 disability for chronic pain conditions. For</p> <p>20 example, Social Security Disability insurance</p> <p>21 today, there are more than 8 million people</p> <p>22 enrolled in Social Security Disability</p> <p>23 insurance, primarily for chronic pain</p> <p>24 conditions.</p> <p>25 So I believe that I can</p>

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<p>1 extrapolate that to include Cuyahoga and</p> <p>2 Summit Counties, that there are individuals</p> <p>3 there who -- with chronic conditions who have</p> <p>4 gone on disability.</p> <p>5 Q. Have you done the exercise of</p> <p>6 extrapolating specifically to Cuyahoga and</p> <p>7 Summit Counties?</p> <p>8 A. Do you mean a quantitative</p> <p>9 analysis?</p> <p>10 Q. Yes.</p> <p>11 A. No.</p> <p>12 Q. Is it your opinion that</p> <p>13 defendants have any role in structuring or</p> <p>14 implementing the Social Security Disability</p> <p>15 network?</p> <p>16 MR. ARBITBLIT: Object to form.</p> <p>17 THE WITNESS: I think</p> <p>18 defendants have had a major role in</p> <p>19 the narrative around how chronic pain</p> <p>20 should be treated for patients who are</p> <p>21 participating in the health care</p> <p>22 system. And as a result, patients</p> <p>23 have been endangered because of being</p> <p>24 exposed to dangerous -- the dangerous</p> <p>25 substance that is opioids.</p>	<p>1 These are all pretty</p> <p>2 qualitative, would you agree?</p> <p>3 MR. ARBITBLIT: Object to form.</p> <p>4 THE WITNESS: Yes.</p> <p>5 QUESTIONS BY MR. TSAI:</p> <p>6 Q. Can you point to a specific</p> <p>7 instance, act, that fits the scenario that</p> <p>8 you've outlined?</p> <p>9 MR. ARBITBLIT: Object to form.</p> <p>10 THE WITNESS: Yeah.</p> <p>11 So in my report, I talk about</p> <p>12 the Wisconsin Pain and Policy Study</p> <p>13 Group, and I provide evidence that</p> <p>14 the -- that industry funded the Pain &</p> <p>15 Policy Study Group, defendants funded</p> <p>16 the Pain & Policy Study Group, over a</p> <p>17 period of many years.</p> <p>18 And the Pain & Policy Study</p> <p>19 Group, in turn, carried out programs</p> <p>20 that benefitted the industry, not only</p> <p>21 by increasing access to opioids and</p> <p>22 limiting regulatory scrutiny {sic},</p> <p>23 but also changing the culture around</p> <p>24 pain treatment and identifying a model</p> <p>25 in which doctors feared retribution if</p>
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<p>1 QUESTIONS BY MR. TSAI:</p> <p>2 Q. Though, that's kind of</p> <p>3 confusing to me. The narrative is -- it's a</p> <p>4 very broad term.</p> <p>5 A. Uh-huh.</p> <p>6 Q. Can you point to any specific</p> <p>7 instance where any conduct by a defendant</p> <p>8 caused an individual within the disability</p> <p>9 payment network, for example, Social Security</p> <p>10 Disability, to have been forced to take their</p> <p>11 particular opioid medication?</p> <p>12 MR. ARBITBLIT: Object to form.</p> <p>13 THE WITNESS: So I think</p> <p>14 defendants have been involved in the</p> <p>15 change, the cultural change, in our</p> <p>16 conceptualization of pain and have</p> <p>17 created a climate in which doctors</p> <p>18 have been forced to treat pain with</p> <p>19 opioids, such that individuals who are</p> <p>20 on disability and get care for their</p> <p>21 chronic pain are at increased risk to</p> <p>22 be exposed to opioids.</p> <p>23 QUESTIONS BY MR. TSAI:</p> <p>24 Q. So you talked about climate,</p> <p>25 the culture and narrative.</p>	<p>1 they didn't use opioids to treat pain.</p> <p>2 QUESTIONS BY MR. TSAI:</p> <p>3 Q. Can you point to any instance</p> <p>4 where anyone providing funds had a role in</p> <p>5 the design and conduct of the specific study</p> <p>6 or program that you're referring to?</p> <p>7 MR. ARBITBLIT: Object to form.</p> <p>8 THE WITNESS: On October 9,</p> <p>9 2002, Joranson wrote to Mr. Kaiko, a</p> <p>10 Purdue representative, quote, "For the</p> <p>11 past several years, without your</p> <p>12 support, some of the progress reported</p> <p>13 below would not have been possible,"</p> <p>14 end quote.</p> <p>15 QUESTIONS BY MR. TSAI:</p> <p>16 Q. And in your view is that</p> <p>17 designing and conducting the study?</p> <p>18 MR. ARBITBLIT: Object to form.</p> <p>19 THE WITNESS: It's not a study</p> <p>20 they're referring to. It's the model</p> <p>21 policy rolled out by the Pain & Policy</p> <p>22 Study Group, which had enormous</p> <p>23 influence in the way that pain was</p> <p>24 treated and is still treated today --</p> <p>25</p>

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<p>1 So those are the types of</p> <p>2 things I'm talking about.</p> <p>3 QUESTIONS BY MR. TSAI:</p> <p>4 Q. What about hospital</p> <p>5 administrators, do they have an important</p> <p>6 role in ordaining and mandating protocols and</p> <p>7 algorithms as you've referred to?</p> <p>8 A. Hospital administrators have an</p> <p>9 important role in that, but, again, any role</p> <p>10 that they played, I believe, was as unwitting</p> <p>11 accomplices in the deliberate</p> <p>12 misrepresentation of the benefits of opioids</p> <p>13 and their risks by the defendants.</p> <p>14 Q. Third-party payers, health</p> <p>15 insurance companies, they have an important</p> <p>16 role in ordaining the mandates and the</p> <p>17 protocols and the algorithms within the</p> <p>18 industrialized medicine system that you</p> <p>19 referred to?</p> <p>20 A. Yes, they do.</p> <p>21 Q. Okay. And when you say that,</p> <p>22 you know, there's a doctor, he or she feels</p> <p>23 enormous pressure to make -- satisfy his or</p> <p>24 her patients, get them quickly out, having</p> <p>25 industrial line, like an assembly line, who</p>	<p>1 So there was overall enormous</p> <p>2 pressure on doctors and on the system</p> <p>3 to prescribe opioids even for minor</p> <p>4 and chronic pain conditions in the</p> <p>5 absence of evidence because that</p> <p>6 evidence was misrepresented to all of</p> <p>7 these various parties by the</p> <p>8 defendants.</p> <p>9 QUESTIONS BY MR. TSAI:</p> <p>10 Q. Have you done any analysis --</p> <p>11 do you have any other basis to reliably rule</p> <p>12 out the likelihood that there are these</p> <p>13 pressures on prescribing doctors following</p> <p>14 protocols and algorithms that came from</p> <p>15 sources that had nothing to do with</p> <p>16 defendants?</p> <p>17 MR. ARBITBLIT: Object to form.</p> <p>18 THE WITNESS: I have the lived</p> <p>19 experience. I got my degree in</p> <p>20 medicine in the early 1990s, and I</p> <p>21 lived through these, you know, past</p> <p>22 two and a half decades, and I</p> <p>23 personally felt the pressures from</p> <p>24 entities like the Joint Commission in</p> <p>25 order to practice in a certain way.</p>
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<p>1 is that pressure coming from?</p> <p>2 MR. ARBITBLIT: Object to form.</p> <p>3 THE WITNESS: That pressure</p> <p>4 comes from the patients themselves and</p> <p>5 the desire of the doctor to do a good</p> <p>6 job, and usually people who go into</p> <p>7 medicine are people who want to have</p> <p>8 quality relationships with their</p> <p>9 patients and feel like they help their</p> <p>10 patients. But there are also</p> <p>11 institutional pressures on doctors to</p> <p>12 have good doctor/patient satisfaction</p> <p>13 surveys.</p> <p>14 And there's also importantly</p> <p>15 patients' expectations around what</p> <p>16 they expect the doctor will provide to</p> <p>17 them when they see that doctor.</p> <p>18 And because of the defendants'</p> <p>19 actions, patients came to expect that</p> <p>20 when they had pain, they should get an</p> <p>21 opioid from their doctor. And we do</p> <p>22 know that there are data showing that</p> <p>23 when patients' expectations are not</p> <p>24 met, they're more likely to rate that</p> <p>25 doctor poorly.</p>	<p>1 QUESTIONS BY MR. TSAI:</p> <p>2 Q. And have you done any</p> <p>3 quantitative analysis to tease out, let's</p> <p>4 say, the role of hospital administrators, or</p> <p>5 the role of third-party payers, in any</p> <p>6 specific opioid prescribing decision of any</p> <p>7 doctor in Cuyahoga and Summit County?</p> <p>8 MR. ARBITBLIT: Object to form.</p> <p>9 THE WITNESS: No.</p> <p>10 QUESTIONS BY MR. TSAI:</p> <p>11 Q. So moving on, just briefly, you</p> <p>12 talked about the CME that you attended. It</p> <p>13 was back in 2001.</p> <p>14 A. Yes.</p> <p>15 Q. So after attending that CME,</p> <p>16 you didn't suddenly lose your independent</p> <p>17 medical judgment, right?</p> <p>18 You still had your own</p> <p>19 independent medical judgment, you agree?</p> <p>20 A. CME courses have an enormous</p> <p>21 influence on the information that doctors</p> <p>22 acquire on which to base their medical</p> <p>23 judgment.</p> <p>24 So I didn't lose my medical</p> <p>25 judgment, but I can only make judgment based</p>

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<p>1 on the information that I have and the</p> <p>2 misrepresentation at that CME and others like</p> <p>3 it across the country.</p> <p>4 Q. And you invoke your personal</p> <p>5 experience?</p> <p>6 A. Yes.</p> <p>7 Q. So you didn't forget all of</p> <p>8 your prior medical education and training</p> <p>9 after leaving that -- how long was that</p> <p>10 session? One hour? Day long?</p> <p>11 A. (Witness nods head.)</p> <p>12 MR. ARBITBLIT: Objection.</p> <p>13 QUESTIONS BY MR. TSAI:</p> <p>14 Q. Did you forget your medical</p> <p>15 education and training?</p> <p>16 MR. ARBITBLIT: Object to form.</p> <p>17 THE WITNESS: Could you specify</p> <p>18 what medical education and training</p> <p>19 you're referring to?</p> <p>20 QUESTIONS BY MR. TSAI:</p> <p>21 Q. Yeah. Your medical school,</p> <p>22 your residency, your fellowship, all of your</p> <p>23 experience in the clinical setting, did the</p> <p>24 CME make you forget all of that?</p> <p>25 MR. ARBITBLIT: Object to form.</p>	<p>1 that you can based on the scientific evidence</p> <p>2 that's available --</p> <p>3 MR. ARBITBLIT: Object to form.</p> <p>4 QUESTIONS BY MR. TSAI:</p> <p>5 Q. -- at the time of prescription;</p> <p>6 do you agree with that?</p> <p>7 MR. ARBITBLIT: Object to form.</p> <p>8 THE WITNESS: As long as the</p> <p>9 science is being accurately</p> <p>10 represented.</p> <p>11 QUESTIONS BY MR. TSAI:</p> <p>12 Q. All right. So going back to</p> <p>13 your TED Talk, if you could turn to page 5 of</p> <p>14 that transcript?</p> <p>15 A. Yeah.</p> <p>16 Q. So starting on page 11, you</p> <p>17 say --</p> <p>18 A. Page 5 or page 11?</p> <p>19 Q. Sorry, starting on page --</p> <p>20 line 11 of page 5, you say, "The second big</p> <p>21 invisible force driving this opioid epidemic</p> <p>22 is the medicalization of poverty."</p> <p>23 Do you see that?</p> <p>24 A. Yes.</p> <p>25 Q. Is it your opinion now that a</p>
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<p>1 THE WITNESS: I didn't forget</p> <p>2 it, but medicine is a discipline in</p> <p>3 which we must keep up with the science</p> <p>4 as it evolves, and a very busy</p> <p>5 clinician, including myself, does not</p> <p>6 have the time to read every single</p> <p>7 peer-reviewed article and dig into who</p> <p>8 funded it or whether or not they</p> <p>9 accurately represented their</p> <p>10 information.</p> <p>11 So we rely on continuing</p> <p>12 medical education courses in order to</p> <p>13 acquire that knowledge. So when I</p> <p>14 went to that continuing medical</p> <p>15 education course, I acquired a body of</p> <p>16 knowledge that was not, in fact, based</p> <p>17 in the evidence, that then influenced</p> <p>18 my practice going forward and that of</p> <p>19 my colleagues.</p> <p>20 QUESTIONS BY MR. TSAI:</p> <p>21 Q. And to pick up on what you</p> <p>22 said, you have to keep up -- science evolves,</p> <p>23 medicine evolves.</p> <p>24 So that's how medicine works,</p> <p>25 right? You have to make the best decisions</p>	<p>1 big driver of the opioid epidemic is the</p> <p>2 medicalization of poverty as you stated here</p> <p>3 in 2017?</p> <p>4 A. It's my opinion that the</p> <p>5 medicalization of poverty is a factor in the</p> <p>6 opioid epidemic, but not as big a factor as</p> <p>7 supply.</p> <p>8 Q. Okay. And have you done any</p> <p>9 analysis to quantify the relative</p> <p>10 significance of the contributions of the</p> <p>11 factor of medicalization of poverty, to use</p> <p>12 your words, and prescription opioid supply?</p> <p>13 MR. ARBITBLIT: Object to form.</p> <p>14 THE WITNESS: I have not</p> <p>15 personally done that analysis, but</p> <p>16 there are others who I cite in my</p> <p>17 report who talk about, again, as I've</p> <p>18 answered in a previous question,</p> <p>19 economic factors not being the primary</p> <p>20 driver, and that supply of opioids in</p> <p>21 a given region being the primary</p> <p>22 driver of opioid use disorder and</p> <p>23 opioid overdose in that region.</p> <p>24 QUESTIONS BY MR. TSAI:</p> <p>25 Q. So at this time what percentage</p>

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<p>1 the record. I would like to take a</p> <p>2 quick break. Thanks.</p> <p>3 VIDEOGRAPHER: We're going off</p> <p>4 the record, and the time is 1:37 p.m.</p> <p>5 (Off the record at 1:37 p.m.)</p> <p>6 VIDEOGRAPHER: We are now going</p> <p>7 back on the record, and the time is</p> <p>8 1:56 p.m.</p> <p>9 (Lembke Exhibit 13 marked for</p> <p>10 identification.)</p> <p>11 QUESTIONS BY MR. TSAI:</p> <p>12 Q. So the next exhibit is</p> <p>13 Appendix I to your report, and it has five</p> <p>14 sections. Section B relates to Mallinckrodt.</p> <p>15 Can you turn to that?</p> <p>16 A. Sure.</p> <p>17 Q. So, first of all, have you</p> <p>18 reviewed any information that you can point</p> <p>19 to or have any other basis to say that any of</p> <p>20 the statements that you attribute to</p> <p>21 Mallinckrodt in Appendix I.B of your report</p> <p>22 were actually seen by any specific doctor or</p> <p>23 other person in Cuyahoga and Summit Counties?</p> <p>24 A. I don't have specific examples,</p> <p>25 but I do believe these misrepresentations</p>	<p>1 I spoke with validated that the</p> <p>2 misrepresentations laid out here in</p> <p>3 this section under Mallinckrodt were</p> <p>4 misrepresentations that they had been</p> <p>5 the recipients of in their medical</p> <p>6 training and that had led them to</p> <p>7 prescribe opioids in a way that they</p> <p>8 now realize was not evidence based.</p> <p>9 QUESTIONS BY MR. TSAI:</p> <p>10 Q. Did anyone use the word</p> <p>11 "Mallinckrodt"?</p> <p>12 A. No, not that I recall.</p> <p>13 Q. Did anyone use the word -- any</p> <p>14 of the products that are -- that Mallinckrodt</p> <p>15 made specifically?</p> <p>16 A. Not that I recall.</p> <p>17 Q. Okay. Have you done any</p> <p>18 analysis to determine whether or to what</p> <p>19 extent Mallinckrodt's marketing of opioid</p> <p>20 products, specifically Mallinckrodt,</p> <p>21 influenced prescribing decisions or rates in</p> <p>22 Cuyahoga and Summit Counties?</p> <p>23 MR. ARBITBLIT: Object to form.</p> <p>24 THE WITNESS: Mallinckrodt held</p> <p>25 the Train-the-Trainer events which</p>
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<p>1 were widely disseminated, including in Summit</p> <p>2 and Cuyahoga Counties.</p> <p>3 Q. So are you speculating that</p> <p>4 they would be seen by doctors in Cuyahoga and</p> <p>5 Summit Counties but cannot point to any</p> <p>6 specific basis to back that up? Is that fair</p> <p>7 to say?</p> <p>8 MR. ARBITBLIT: Object to form.</p> <p>9 THE WITNESS: Because these</p> <p>10 misrepresentations were so deeply</p> <p>11 interwoven into medical education, it</p> <p>12 would be hard for me to believe that</p> <p>13 physicians in Summit and Cuyahoga</p> <p>14 Counties hadn't seen these</p> <p>15 misrepresentations, but I cannot point</p> <p>16 to any specific examples.</p> <p>17 QUESTIONS BY MR. TSAI:</p> <p>18 Q. And when you talked to doctors</p> <p>19 after your pair of talks last year in Ohio,</p> <p>20 did any of those doctors who practice in</p> <p>21 Cuyahoga and Summit Counties tell you that</p> <p>22 they relied on any of the statements that you</p> <p>23 attribute to Mallinckrodt specifically?</p> <p>24 MR. ARBITBLIT: Object to form.</p> <p>25 THE WITNESS: The doctors that</p>	<p>1 communicated these misrepresentations</p> <p>2 to individuals who then went</p> <p>3 throughout the country disseminating</p> <p>4 these misrepresentations, and I don't</p> <p>5 have any specific examples, but I</p> <p>6 wouldn't be surprised if they</p> <p>7 disseminated these misrepresentations</p> <p>8 also in Summit and Cuyahoga Counties.</p> <p>9 Also Mallinckrodt promoted a</p> <p>10 book through the CARES Alliance called</p> <p>11 Defeat Chronic Pain Now!, and I</p> <p>12 wouldn't be surprised if that book was</p> <p>13 read by providers in Cuyahoga and</p> <p>14 Summit County and that book contained</p> <p>15 these misrepresentations.</p> <p>16 QUESTIONS BY MR. TSAI:</p> <p>17 Q. So you say you wouldn't be</p> <p>18 surprised, but can you point to anything in</p> <p>19 your materials that you've provided to us</p> <p>20 that specifically isolates the contribution</p> <p>21 of Mallinckrodt's conduct to promotional</p> <p>22 activity with respect to opioid prescribing</p> <p>23 or any adverse event in Cuyahoga and Summit</p> <p>24 County?</p> <p>25 MR. ARBITBLIT: Object to form.</p>

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